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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/777,920	02/07/2001	Jacques Dumas	BAYER 15 P3	6183
23599	7590	08/11/2005	EXAMINER	
MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201			DESAI, RITA J	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/777,920

**Applicant(s)**

DUMAS ET AL.

**Examiner**

Rita J. Desai

**Art Unit**

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-22, 24-30, 34-37, 39, 40, 42 and 45-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22, 24-30, 34-37, 39, 40, 42, 45-49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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**DETAILED ACTION****Restriction Election:-**

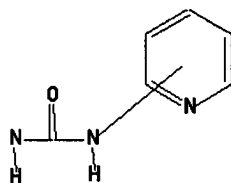
The examiner has clearly given the reasons for restriction.

The classification would depend on the species elected. Which can range from class 560, 562, 546, 548, 549 and so on. The different classes show burdensome search. Even without the different classes it would require different structure searches. This would be burdensome to the PTO.

The Groups would be independent and distinct.

If applicants traverse on the grounds that the inventions are not patentably distinct, applicants should submit evidence or identify such evidence now of record showing the groups to be obvious variants or clearly admit on the record that this is the case. In either instance if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 USC 103 of the other invention.

This is not found persuasive because even that with an ureido group is not applicants' contribution over the prior art!



&gt; S II

SAMPLE SEARCH INITIATED 17:22:19 FILE 'REGISTRY'

SAMPLE SCREEN SEARCH COMPLETED - 2101 TO ITERATE

47.6% PROCESSED 1000 ITERATIONS

50 ANSWERS

INCOMPLETE SEARCH (SYSTEM LIMIT EXCEEDED)

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SEARCH TIME: 00.00.01

FULL FILE PROJECTIONS: ONLINE \*\*COMPLETE\*\*

BATCH \*\*COMPLETE\*\*

PROJECTED ITERATIONS: 39272 TO 44768.

The requirement is still deemed proper and is therefore made FINAL.

Applicant is required to amend the claims to the elected group.

The rejection under 35 USC 112 of claims 1-22, 24-30, 34-37, 39, 39, 40, 42, 45-48 still stands. Applicants arguments are not convincing.

In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

**1) The breadth of the claims:** The instant claims encompass many compounds ranging from an aromatic carbocyclic moiety to an aromatic carbocyclic moiety having many large electron withdrawing and bulky groups substituted on it to a moiety having many heterocyclic rings having many large and various groups hanging from it. These compounds cover a very wide range of compounds.

**2) The nature of the invention:** The invention is a (highly) substituted compound for pharmaceutical use.

**3) The state of the prior art:** the prior art does not teach the various substituted compounds.

**4) The level of one of ordinary skill:** The ordinary artisan is highly skilled.

**5) The level of predictability in the art:** It is unknown what the level of predictability is in the art since there are no working examples either in the specification or in the prior art of compounds doing similar activity. The examples shown do not have any any hetero ring substitutions, see table 7 and compound 104 in the specification.

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8. A compound of claim 1, 2, 3 or 4 wherein A is optionally substituted 2, 3-, 4-, 5-, 6-, 7- or 8-quinolinyl, 1-, 3-, 4-, 5-, 6-, 7-, 8- isoquinolinyl, benzimidazol-5-yl, The compounds are drawn to treating cancer. *Even a substitution of a methyl verses a hydrogen changes the properties, as seen in caffeine and theophylline. These compounds only differ by a methyl group. One is a bronchodilator.*

**6) The amount of direction provided by the inventor:** The inventor provides very little direction in the instant specification. Just a range of data is given for invitro testing and a specific cell line.

**7) The existence of working examples:** The instant specification does not have any working examples.

**8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure:** Since there are no working examples, the amount of experimentation is very high and burdensome. Also, the compounds in table 7 and 107 do not represent the fullest extent of the instant claim 1.

Taking the above eight factors into consideration, it is not seen where the instant specification enables the ordinary artisan to make and/or use the instantly claimed invention.

Thus the rejection still stands.

The rejection of the claims 29, 30, 36 and 48 under 35 USC 112 second para still stands. The arguments are not found to be persuasive.

The Double patenting Rejection over 10788029 still stands.

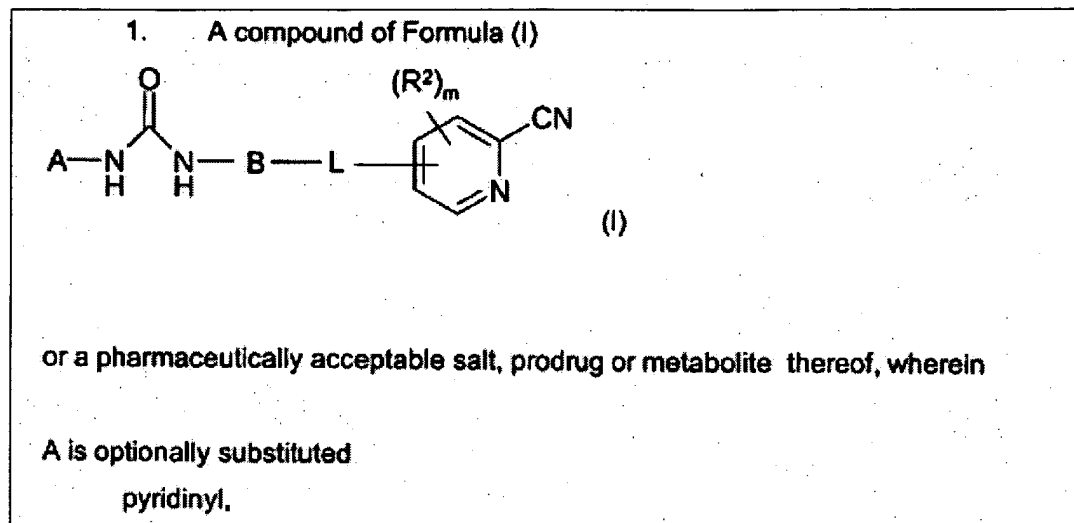
10/788029 claims teach A to be a quinoline or pyridine, and B is a

B is optionally substituted phenyl or naphthyl,

L is O or S,

Claim 1 recites.

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8. A compound of claim 1, 2, 3 or 4 wherein A is optionally substituted 2, 3-, 4-, 5-, 6-, 7- or 8-quinolinyl, 1-, 3-, 4-, 5-, 6-, 7-, 8- isoquinolinyl, benzimidazol-5-yl,

This reads on the restricted group.

The obvious type Double Patenting over 10/895985 and 09/889227 has been withdrawn since they are drawn to phenyl instead of the quinoline or pyridyl group.

New Obvious Type Double Patenting Rejection:

The claims are rejected over US 10/361, 858.

It teaches

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A=pyridinyl, B= naphthyl and M is phenyl, pyridinyl, quinolinyl, isoquinolinyl or not present.

A=isoquinolinyl, B= phenyl and M is phenyl, pyridinyl, quinolinyl, isoquinolinyl or not present.

A= isoquinolinyl, B= pyridinyl and M is phenyl, pyridinyl, quinolinyl, isoquinolinyl or not present.

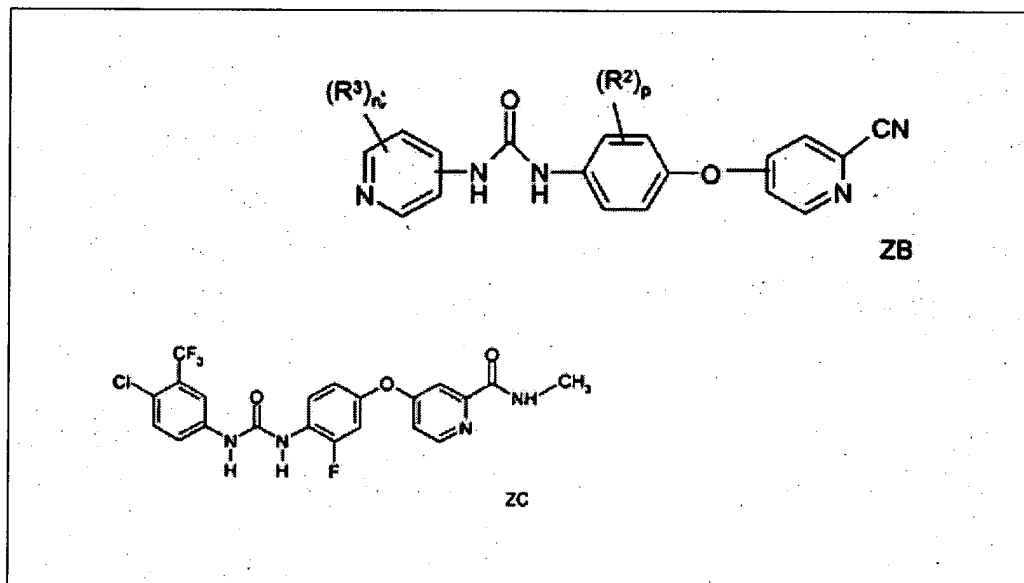
A= isoquinolinyl, B= naphthyl and M is phenyl, pyridinyl, quinolinyl, isoquinolinyl or not present.

A= quinolinyl, B= phenyl and M is phenyl, pyridinyl, quinolinyl, isoquinolinyl or not present.

A= quinolinyl, B= pyridinyl and M is phenyl, pyridinyl, quinolinyl, isoquinolinyl or not present.

A= quinolinyl, B= naphthyl and M is phenyl, pyridinyl, quinolinyl, isoquinolinyl or not present.

Also US 10/848567 which teaches



### Conclusion

The claims are not found to be allowable.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, 9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rita J. Desai  
Primary Examiner  
Art Unit 1625

  
8/8/05

R.D.  
August 8, 2005